K110140

SEP 30 2011

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Traditional 510k – Neurovision Nerve Locator/Monitor Model NV006

510K Summary
In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information
Christine Vergely
Regulatory Affairs Manager
Neurovision Medical Products, Inc.
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Ventura, CA 93003
Ph 805-866-6999
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christie@neurovisionmedical.com

Date of Summary: 5/02/11

Device Identification:
Trade Name: Neurovision Nerve Locator Monitor NV006 (tbd)
Common Name: Nerve Monitor/Locator System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN

Predicate Devices
Neurovision, Nerve Locator/Monitor System Modification NV004 model (K954601)
NuVasive, INS-1 Intraoperative Nerve Surveillance System (K002677)

Device Description
The Neurovision Nerve Locator Monitor Model NV006 is a single channel evoked EMG device for surgical nerve location and monitoring. The device operates exactly as the predicate model NV004. The stimulation range for the predicate device (Model NV004) as a proactive nerve locator is up to 5.0 mA of pulsed nerve stimulation. An accessory cable adds optional "high level" stimulation (Model NV006) ranging from 3.0 to 12 mA.

Intended Use
The Neurovision Nerve Locator Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG Monitor with integrated detecting or warning capability. The device is intended to assist the surgeon in locating motor nerves that are at risk in surgical procedures.

Technological Characteristics of Device in Relation to Predicate Devices
The Neurovision High-Stim Nerve Locator/Monitor modification uses a dedicated stimulation cable assembly, the CSTI-HS, to activate an embedded capability to deliver nerve stimulation at higher levels (to 12 mA pulsed stimulation) as sometimes required for spinal screw testing purposes. The "HighStim" Cable Assembly, which activates higher level stimulation, is provided to the user as an accessory with the NV006 model in addition to the standard Stimulating Cable Assembly (CSTI).

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Table 1: NV004 to NV006 Modification Comparison		
Feature	**NV004 (K954601)**	**NV006 (High-Stim version)**
Indications for Use	Per 510(k)	Same plus addition of spinal procedures
Digital Display	N/A	Provides electrode impedance readings
Firmware	Assembly Language	Same
Logical Algorithm	Neurovision proactive nerve location algorithm	Same
Stim voltage limit	38 v	Same
Stimulation output	Max 5mA, 5 steps, constant current	Max 5mA/12 mA, 10 steps, high range by separate cable. Lowest setting 0.1mA conforms to ISO 60601-2-40
Stim delivered audio	"Tic-tic" audio alert	Same
Stimulation calibration	None	Accurate within 5% of delivered current
EMG	Variable gain	Same
Channels	One	Same
Electrode off	4 beep alarm	Same
Impedance measure	>15 k fixed alert	Actual measurement with digital display
Audio out	Sounder	Speaker
Audio mode	Fixed alarms only	Alarms only, raw EMG only, or both, user select
Audio alarm tone	Beep	Same
Volume	Variable, no zero	Same
Self-test feature	Analog CAP internal	Same
Event LED	Present	Same
Battery LED	Present	Same
Data out	Analog raw EMG out	Serial USB out; raw EMG and status data
Data collection	Digital PC oscilloscope	Dedicated digital EMGView oscilloscope software (K102861)
Cable Assembly	EMG and Stimulation (low)	Same plus additional High-Stimulation cable
Stimulating Lead Wire	Reusable / user sterilizable wire, disposable sterile	Disposable sterile wire
Circuitry	Analog/digital	Same
Layout	Thru-hole components	Same plus surface mount

Isolation	Per design	Improved physical isolation; shielding by Opto Isolators
High Stim LED	N/A	Activated when High Stim cable in use
Power	20 v AC Power Supply/Charger; not certified	12 V DC Power Supply/Charger; certified
Nerve Location Indication	Detection circuitry always active	Detection circuitry active only during stimulation. Helps prevent false alarms
Laryngeal Surface electrode-accessory	Accessory sold separately	Cleared through K003745
Stimulating Hemostat-accessory	Accessory included with System	Cleared through K895676
Hydrogel Ground-accessory	Accessory sold separately	Cleared through K092744 and K110138
Needle Ground Electrode - accessory	Accessory sold separately	Cleared through K091056

Table 2: Substantial Equivalence Comparison

	Predicate	**Predicate**	**Subject Device**
Feature	**Neurovision Nerve Locator/Monitor System Modification NV004** (K954601)	**NuVasive INS-1** (K002677)	**Neurovision Nerve Locator Monitor Model NV006**
Description	Evoked EMG nerve locator/monitor	Evoked EMG nerve locator/monitor	Evoked EMG nerve locator/monitor
Intended Use	The Neurovision Nerve Locator/Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG monitor with integrated detecting and warning capability. This device is intended for use in surgical procedures where motor nerves are	The INS-1 Intraoperative Nerve Surveillance System is intended to provide intraoperative electromyographic (EMG) surveillance to assist in the location and evaluation of spinal nerves during percutaneous surgery of the spine, by	The Neurovision Nerve Locator Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG Monitor with integrated detecting or warning

	at risk to assist the surgeon in locating these nerves. This device is intended for use only by qualified, trained medical practioners who perform operative surgery and fully understand that this device is only and adjuvant to proper surgical technique and good surgical judgment.	administration of low amperage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves. The INS-1 System is designed for use in conjunction with the Nuvasive Guided Spinal Arthroscopy System to assist in gaining controlled percutaneous access to the spinal nerve root, foramina, intervertebral disk, and surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomical restrictions safely permit.	capability. The device is intended to assist the surgeon in locating motor nerves that are at risk in surgical procedures.
Stimulation Intensity	150 microsecond square pulse, 4 per second, (0.1-5.0 mA, 10 steps); Maximum 42 VDC, 5 mA	200 microsecond square pulse, 4 per second, 0.4mA -12mA, Maximum 240 VDC	150 microsecond square pulse, 4 per second, 0.1-5.0 mA (Low) and 3.0-12 mA (High) 10 steps; Maximum 42 VDC, 12 mA

Performance Testing
Preclinical testing verified the design of this device and that all specified requirements were fulfilled

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurovision Medical Products, Inc.
c/o Ms. Christine Vergely
Regulatory Manager
2225 Sperry Avenue, Suite 1000
Ventura, CA 93003

SEP 30 2011

Re: K110140
Trade/Device Name: Nerve Locator Monitor (NV006)
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN
Dated: September 20, 2011
Received: September 22, 2011

Dear Ms. Vergely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 110140

Indications for Use

510(k) Number (if known): K110140

Device Name: Neurovision Nerve Locator/Monitor Model NV006

Indications for Use:

The Neurovision Nerve Locator Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG Monitor with integrated detecting or warning capability. The device is intended to assist the surgeon in locating motor nerves that are at risk in surgical procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K110140